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## **Draft Guidance Classification of Materials**

### **1. Purpose**

This guidance describes the procedure used to classify materials as synthetic or nonsynthetic, and as agricultural or nonagricultural, under the USDA organic regulations.

### **2. Scope**

This guidance applies to all National Organic Program (NOP) certifying agents, certified operations, material evaluation programs, and other organic industry stakeholders.

### **3. Background**

#### **3.1 The National List of Allowed and Prohibited Substances**

The Organic Foods Production Act of 1990 (OFPA) authorizes the USDA to establish the National List of Allowed and Prohibited Substances (National List). The National List is implemented in the USDA organic regulations at 7 CFR 205.600-607.

Under the OFPA, the National List must contain an itemization of each synthetic substance that is permitted and each natural substance that is prohibited for organic production. Due to this unique construction of the National List, definitions and classification are important to determine whether a substance is allowed or prohibited in organic production, whether it needs to be included on the National List, and where on the National List it should be placed.

For the purposes of this guidance, we are using the synonymous terms “substance” and “material” interchangeably, as “substance” is the term for items included on the National List, and “material” is the term more commonly used within the organic community.

For organic crop and livestock production, nonsynthetic (natural) materials are allowed unless specifically prohibited. Synthetic materials are prohibited unless they appear on the National List at section 205.601 for crop production or section 205.603 for livestock production.

For handling, the National List includes nonorganic substances that may be used in or on processed products. Section 205.605 includes the nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” Nonagricultural substances may be classified as nonsynthetic at paragraph (a) or synthetic at paragraph (b). Section 205.606 of the National List includes the nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.” Substances included in section 205.606 may be used in organic products only when the product is not commercially available in organic form.



For the vast majority of materials, classification as synthetic or nonsynthetic, or as agricultural or nonagricultural, is straightforward; however, other materials are more complicated to classify which can result in inconsistent interpretations. Some materials may be considered synthetic due to chemical changes which occur during manufacturing, while others substances may be classified as synthetic due to addition of small amounts of synthetic ingredients.

For livestock production, the classification of a substance used in livestock feed as agricultural or nonagricultural is important for determining whether the feed ingredient must be sourced in a certified organic form. For example, agricultural feed ingredients that must be certified organic include all feed and forage crops, and additives such as molasses, rice hulls, and vegetable oils.

For the handling or processing of organic agricultural products, the National List includes a list of agricultural and nonagricultural substances which are allowed in the handling of organic agricultural products. Nonagricultural substances are differentiated as either nonsynthetic (natural) or synthetic. Thus, the proper determination of a substance as agricultural or nonagricultural, or as synthetic or natural is important for proper placement on the National List.

This guidance implements previous recommendations and existing practices of the National Organic Standards Board (NOSB) on the classification of materials. This guidance also provides clarification of the existing practices used to classify materials, as currently applied by the NOSB, accredited certifying agents, and material evaluation programs.

In implementing the NOSB's recommendation, the NOP has not amended the regulations with new definitions, but has provided explanatory definitions within the guidance document to be used when appropriate. Some definitions that were provided in the April 2011 NOSB Formal Recommendation on Classification of Materials have been updated or amended within the guidance for clarity.

## **4. Policy**

### **4.1 Inputs for Organic Crop Production**

Input materials for organic crop production are classified as nonsynthetic or synthetic according to the classification decision tree, NOP 5033-1. Synthetic substances allowed for use in organic crop production are included on the National List at section 205.601. Natural substances prohibited for use in organic crop production are included on the National List at section 205.602.

A list of allowed natural and synthetic materials for organic crop production is available at NOP 5034-1, Materials for Organic Crop Production. For more information on the use of this list, refer to NOP 5034.

### **4.2 Inputs for Organic Livestock Production**

Inputs for organic livestock production are classified as nonsynthetic or synthetic according to the classification decision tree, NOP 5033-1. Synthetic substances allowed for use in organic livestock production are included on the National List at section 205.603. Natural substances prohibited for use in organic livestock production are included on the National List at section 205.604.



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Agricultural livestock feed ingredients must be certified organic (§ 205.237(a)). Livestock feed ingredients should be first classified as agricultural or nonagricultural according to the classification decision tree, NOP 5033-2, to determine whether they are required to be certified organic. Substances that are determined to be nonagricultural may be further classified according to NOP 5033-1 to determine whether they are synthetic or nonsynthetic.

### **4.3 Inputs for Organic Handling and Processing**

Petitioned ingredients and processing aids for handling and processing are classified by the NOSB to determine placement of substances on the National List, sections 205.605-205.606.

Substances must first be classified as agricultural or nonagricultural according to the classification decision tree, NOP 5033-2. Nonagricultural substances should be further classified as nonsynthetic or synthetic to determine placement on section 205.605(a) or 205.605(b), respectively.

### **4.4 Eligibility for Organic Certification**

This guidance does not determine the eligibility of a substance for organic certification.

If a substance contains or is made up of agricultural ingredients and can meet the USDA organic production, handling, processing and labeling standards, it may be eligible to be certified under the USDA organic regulations.

### **4.5 Materials Derived from Agricultural Products**

Materials derived from agricultural products may be classified as agricultural or nonagricultural, depending on the manufacturing and processing methods used.

The decision tree, NOP 5033-1, includes questions to differentiate between chemical reactions caused by naturally occurring biological processes, such as composting, fermentation, or enzymatic digestion; and by heating or burning biological matter (e.g. cooking, baking, etc.).

Agricultural materials which are chemically changed due to allowed agricultural processing methods (e.g., cooking, baking, etc.) do not result in classification of the processed agricultural product as synthetic.

### **4.6 Extraction of Nonorganic Materials**

Some materials are produced using manufacturing processes that involve separation techniques, such as the steam distillation of oil from plant leaves. Separation and extraction methods may include, but are not limited to, distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g., filtration, crushing, centrifugation, or gravity separation).

For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:



- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

#### **4.7 Products of Naturally Occurring Biological Processes**

Products of naturally occurring biological processes, such as fermentation and composting are considered natural and nonsynthetic. Examples of nonsynthetic materials produced from naturally occurring biological processes include vinegar, citric acid, compost, gibberellic acid, and spinosad. Additional examples are provided in Table 1 of NOP 5033-1.

#### **4.8 Burning or Combustion**

Heating or burning of biological matter (e.g., plant or animal material) is considered a natural process that does not result in classification of ash as synthetic. For example, ash from manure burning is classified as a prohibited nonsynthetic substance at section 205.602 of the National List. The use of other types of ash must comply with the soil fertility and crop nutrient management practice standard at section 205.203 of the NOP.

Heating or burning of non-biological matter (e.g., minerals) to cause a chemical reaction results in classification of the substance as synthetic. For example, limestone (calcium carbonate,  $\text{CaCO}_3$ ) heated to release carbon dioxide and produce quicklime (calcium oxide,  $\text{CaO}$ ) is classified as a synthetic process.

### **5. Procedure**

#### **5.1 Inputs for Organic Crop Production**

Classification of input materials for use in organic crop production should be made according to decision tree NOP 5033-1 (synthetic or nonsynthetic).

#### **5.2 Inputs for Organic Livestock Production**

Classification of input materials used for organic livestock production should be made according to decision tree NOP 5033-1 (synthetic or nonsynthetic).

For animal feed ingredients, substances should be classified first as agricultural or nonagricultural according to decision tree NOP 5033-2. Feed ingredients classified as agricultural do not need to be further classified since they are required to be used in organic form.



### 5.3 Inputs for Organic Handling and Processing

Classification of input materials used for organic handling or processing should be made according to decision trees NOP 5033-1 and NOP 5033-2. For handling materials, classification as nonagricultural or agricultural according to NOP 5033-2 is made first to determine placement on 205.605 or 205.606. Substances classified as nonagricultural should be further classified as nonsynthetic or synthetic for determining placement on section 205.605(a) or 205.605(b), respectively.

Materials classified as agricultural must be certified organic when used in products labeled “organic,” with the exception of agricultural ingredients included at section 205.606 if they are not commercially available as organic.

Materials classified as agricultural may be used in products labeled “made with organic (specified ingredients or food group(s))” according to the provisions in section 205.301(c).

Examples of classification decisions are provided in each decision tree.

National List Sections	Type of Use	Classification Determination	Decision Tree
205.601/205.602	Crop Production	Synthetic / Nonsynthetic	NOP 5033-1
205.603/205.604	Livestock Production	Synthetic / Nonsynthetic	NOP 5033-1
205.603/205.604	Livestock Feed Ingredients	Agricultural / Nonagricultural	NOP 5033-2
205.605/205.606	Handling	Agricultural / Nonagricultural	NOP 5033-2
205.605(a)/205.605(b)	Handling – Nonagricultural	Nonsynthetic / Synthetic	NOP 5033-1

## 6. References

### 6.1 USDA Organic Regulations

#### [§ 205.2 Terms defined.](#)

*Agricultural inputs.* All substances or materials used in the production or handling of organic agricultural products.

*Agricultural product.* Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

*Allowed synthetic.* A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

*Ingredient.* Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

*Nonagricultural substance.* A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a



nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

*Nonsynthetic (natural).* A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

*Prohibited substance.* A substance the use of which in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations of this part.

*Synthetic.* A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

## **6.2 Organic Foods Productions Act of 1990 (as amended)**

### **SEC. 2103 [7 U.S.C. 6502] DEFINITIONS.**

(21) SYNTHETIC.—The term “synthetic” means a substances that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

## **6.3 NOP Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations**

NOP 5034: Materials for Organic Crop Production (Draft Guidance)

NOP 5034-1: Materials for Organic Crop Production (Draft Guidance)

NOP 5034-2: Appendix of Prohibited Materials for Organic Crop Production (Draft Guidance)

Policy Memo 11-4: Evaluation of Materials used in Organic Crop, Livestock and Handling Operations. October 31, 2011.

## **6.4 NOSB Recommendations**

NOSB Formal Recommendation, Classification of Materials, April 29, 2011

NOSB Formal Recommendation, Classification of Materials, May 24, 2010

NOSB Formal Recommendation, Classification of Materials, November 5, 2009

NOSB Formal Recommendation, NOSB guidance for the review of synthetic and non-synthetic substances, August 27, 2005

## **6.5 Other**



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Effective Date: TBD  
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NOP Memorandum to the National Organic Standards Board, Request for Clarification of “Other Ingredients” in Processed Organic Products, November 23, 2011;

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5095484>.